

Inclusion of perfluorinated carboxylic acids (C9-14 PFCA) in Annex XVII REACH

TÜV Rheinland LGA Products –Information

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With Commission Regulation (EU) 2021/1297 of 4 August 2021 amending Annex XVII, entry 68, REACH Regulation now regulates linear and branched perfluorinated carboxylic acids with 9 to 14 carbon atoms (C9-C14 PFCA), their salts and related substances, in articles, substances and mixtures. The Regulation will come into force 25 February 2023.

The Committee for Risk Assessment (RAC) thus agreed with the inclusion of C9-C14 PFCAs, corresponding concentration limits and suggested exemptions proposed by Germany and Sweden, because the proposed restriction is not intended to prevent the production of fluorochemicals with six or fewer carbon atoms in the molecular chain.

The previous Regulation for PFOA, salts and their related compounds were transferred to Regulation (EU) 2019/1021 (POP Regulation) by Delegated Regulation 2020/784 in April 2020.

Some but not all exemptions listed in Annex XVII entry 68 REACH were taken over to POP Annex I Part A. *The previous entry 68 of Annex XVII REACH has been replaced by the above amendment to Regulation (EU) 2019/1021.*

The exemptions that apply to the use of PFOA, its salts and PFOA-related compounds under the amendment to Regulation (EU) 2019/1021 should also apply to C9-C14 PFCA, its salts and related substances under the same conditions, as both groups of substances are impurities in the manufacture of fluorochemicals.

AMENDMENTS ENTRY 68 - C9-C14 PFCA, THEIR SALTS AND RELATED SUBSTANCES

	Regulation	Validity	Substances and mixtures	Articles
C9-C14 PFCA, and their salts	REACH Annex XVII Entry 68	25. Feb. 2023	< \sum 25 $\mu\text{g}/\text{kg}$	< \sum 25 $\mu\text{g}/\text{kg}$
C9-C14 PFCA related substances			< \sum 260 $\mu\text{g}/\text{kg}$	< \sum 260 $\mu\text{g}/\text{kg}$

For further details please refer to the [Regulation \(EU\) 2021/1297](#).

The substance group of C9-C14 PFCAs, their salts and related substances regulated can be regarded as UVCB substance, substance with unknown or variable composition (UVCB = Unknown or Variable composition, Complex reaction products or Biological materials).

As in some similar cases, the situation arises that it is not always possible to decide unambiguously whether certain substances are to be assigned to this group or not. Analytically, the determination of such an undefined substance class is also predictably incomplete.

NOTE

We recommend you to identify in which of your products these C9-C14 PFCAs are contained, to identify alternatives and to change the affected products accordingly.

Please note that similar efforts to regulate and ban perfluorinated compounds in products, substances and mixtures also exist outside the European Union.

Further information on current legal changes can also be found on our homepage at www.tuv.com or <https://www.tuv.com/regulations-and-standards/en/>.

OTHER INFORMATIONEN

In recent years, legislation and numerous non-governmental organisations in Europe and United states have brought the issue of fluorocarbons and perfluorinated compounds to the attention of consumers, brands and retailers. Uniform regulations for these substance class(es) currently exist in Europe in Regulation (EC) No. 1907/2006 REACH (Candidate List) and POP Regulation, among others.

Particularly critical are the relatively mobile perfluorinated alkyl substances (PFAS), which are released as by-products from the manufacturing process during application and may still be present in traces in the products. Their release into the environment should be avoided due to their persistence and possible toxicological effects.

Perfluorinated alkyl substances (PFAS) are a subgroup of fluorocarbons, according to OECD there are more than 4700 substances. Due to their special properties, they have been used in many industrial sectors and also in the household since the 1960s.

The unique properties, water and grease repellent at the same time, and the high thermal and chemical stability enable various applications, e.g. as emulsifiers in the production of perfluoropolymers ("Teflon pan"), as surfactants in electroplating (chrome plating) and fire extinguishing foams, in the production of semiconductors or also in photographic processes.

Furthermore, PFAS are used in a number of consumer products, such as paints, leather and textile coatings, (outdoor) clothing, footwear, carpets, packaging, ski wax, floor and car care products, as well as in the production of papers with dirt-, grease- and water-repellent properties and as components of impregnating agents and lubricants.

The original advantage of PFASs, stability and longevity (persistence), is also a disadvantage, as many of these substances are toxic and accumulate in the food chain to varying degrees (bioaccumulability).

CURRENT REGULATION ON PFCA UNDER POP

The best-known substance groups of PFAS are those with a chain length of eight carbon atoms (C8):

- Perfluorinated alkyl sulfonates - best known representative: Perfluorooctane sulfonic acid (PFOS).
- Perfluorinated carboxylic acids - best known representative: Perfluorooctanoic acid (PFOA).

PFOA and PFOS are currently regulated by law under the POP Regulation Annex 1 Part A.

	Legislation	Substances & mixtures	Coated articles	Uncoated articles
PFOA, its salts	POP Annex I Part A	$\leq 25 \mu\text{g/kg}$	$\leq 25 \mu\text{g/kg}$	$\leq 25 \mu\text{g/kg}$
PFOA-related compounds		$\leq \sum 1000 \mu\text{g/kg}$	$\leq \sum 1000 \mu\text{g/kg}$	$\leq \sum 1000 \mu\text{g/kg}$
PFOS and its derivatives	POP Annex I Part A	$\leq 0.001 \%$	$< 1 \mu\text{g/m}^2$	$< 0.1 \%^*$

* Semi-finished products and products

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